

**DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS OR BECAUSE OF SUBSTITUTION<sup>1</sup>**

**156. Adulteration and misbranding of Elixir Sodium Salicylate Compound. U. S. v. Standard Pharmacal Co. Plea of nolo contendere. Fine, \$25. (F. D. C. No. 956. Sample No. 55545-D.)**

This product was represented to be a drug the name of which is recognized in the National Formulary. It contained potassium iodide in excess of the amount specified in the National Formulary, and in excess of the amount declared on its label.

On May 14, 1940, the United States attorney for the Northern District of Illinois filed an information against the Standard Pharmacal Co., a corporation, Chicago, Ill., alleging shipment by said company on or about July 31, 1939, from the State of Illinois into the State of Indiana, of a quantity of elixir sodium salicylate compound which was adulterated and misbranded.

Adulteration was alleged in that the article was represented as a drug the name of which is recognized in an official compendium, the National Formulary, and its strength differed from the standard set forth in said compendium in that 1,000 cubic centimeters of the article contained not less than 20.2 grams of potassium iodide, equivalent to 9.19 grains per fluid ounce; whereas the National Formulary provides that compound elixir of sodium salicylate shall contain in each 1,000 cubic centimeters 15 grams of potassium iodide, equivalent to 6.84 grains per fluid ounce and the difference in strength of the article from the said standard was not stated plainly on the label.

Misbranding was alleged in that the representation on the label that each fluid ounce represented  $3\frac{3}{4}$  grains of potassium iodide was false and misleading since each fluid ounce of the article contained not less than 9.19 grains of potassium iodide.

On June 24, 1940, a plea of nolo contendere was entered on behalf of the defendant, and the court imposed a fine of \$25.

**157. Adulteration and misbranding of mineral oil. U. S. v. 1,149 Packages of Mineral Oil. Default decree of condemnation and destruction. (F. D. C. No. 1944. Sample No. 2344-E.)**

This product failed to comply with the standard prescribed by the United States Pharmacopoeia since tests showed that it contained carbonizable substances; whereas the pharmacopoeia provides that white mineral oil shall be free from such substances.

On May 16, 1940, the United States attorney for the District of Massachusetts filed a libel against 1,149 packages of mineral oil at Springfield, Mass., alleging that the article had been shipped in interstate commerce on or about April 5, 1940, by the Tyler Products Co. from Pawtucket, R. I.; and charging that it was adulterated and misbranded. It was labeled in part: "Federal Mineral Oil \* \* \* U. S. P. Standard."

Adulteration was alleged in that the article purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia and its quality or purity fell below the standard set forth in the pharmacopoeia and its difference from the standard was not plainly stated on the label.

It was alleged to be misbranded in that the representations in the label that it was mineral oil of United States Pharmacopoeial standard, was false and misleading since it did not comply with the tests laid down in the pharmacopoeia for mineral oil.

On June 24, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**158. Adulteration and misbranding of mineral oil. U. S. v. 117 Bottles of Russian Oil U. S. P. Mineral Oil. Default decree of condemnation and destruction. (F. D. C. No. 1779. Sample No. 2247-E.)**

This product was light mineral oil and not heavy mineral oil as indicated by its labeling.

On April 11, 1940, the United States attorney for the District of Rhode Island filed a libel against 117 bottles of mineral oil at Providence, R. I., alleging that the article had been shipped in interstate commerce on or about February 20, 1940, by Diamond Drug & Magnesia Co., Boston, Mass.; and charging that it

<sup>1</sup> See also N. J. Nos. 146, 182, and 215.